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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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EXAMINER

SWARTZ, RODNEY P

ART UNIT PAPER NUMBER

1645

DATE MAILED: 12/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/009,384

Applicant(s)

GENNARO ET AL.

Examiner

Rodney P. Swartz, Ph.D.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 October 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 11-36 is/are pending in the application.
- 4a) Of the above claim(s) 21-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 11-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-8,21-36 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicants' Response to Office Action, received 7 October 2005, is acknowledged.

Claims 1, 11, and 13-28 have been amended. Claims 9 and 10 have been canceled.

2. Claims 1-8 and 11-36 are pending. Claims 21-36 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.

3. Claims 1-8 and 11-20 are under consideration.

Rejections Moot/Withdrawn

4. The rejection of claims 9 and 10 under 35 U.S.C. 112, first paragraph, scope of enablement for vaccines, is moot in light of the cancelation of the claims.

5. The rejection of claims 9 and 10 under 35 U.S.C. 112, second paragraph, indefiniteness for specific properties and number/identity of conservatively substitutes residues, is moot in light of the cancelation of the claims.

Rejections Maintained

6. The rejection of claims 17-20 under 35 U.S.C. 112, first paragraph, scope of enablement for diagnostic methods utilizing polypeptides, is maintained.

Applicants argue that one skilled in the art would have expected that at least a substantial number of the *M. tuberculosis* polypeptides identified by the analyses described in the example on pages 13-22 as being secreted polypeptides would be useful for diagnosis of tuberculosis. In support, applicants submit a scientific article published after the priority date of the instant application. Applicants argue that the article shows that the claimed method is valid as a method of diagnosis that a subject has or is susceptible to *M. tuberculosis* infection utilizing the polypeptides MTSP1, MTSP21, MTSP23, MTSP36, and MTSP43 or a functional segment thereof.

Art Unit: 1645

The examiner has considered applicants' arguments and the cited reference provided by applicants, but does not find them persuasive.

As stated in the original rejection, the specification is merely speculative concerning success of an individual polypeptide as a diagnostic composition in methods for specifically detecting *M. tuberculosis* infected hosts or hosts susceptibility to *M. tuberculosis*.

The cited reference (Amor et al), page 144, second column, lines 2-5 states "For two proteins (Rv0203 and Rv0603), we found no difference between serum antibody levels measured in untreated TB patients relative to control patients having lung disease other than TB." Thus, two of the claimed polypeptides MTSP1 (Rv0603) and MTSP43 (Rv0203) did not distinguish between a TB patient and a patient having lung disease other than TB. The remaining claimed polypeptides produced low reactivity with patient sera, i.e., at best 9/50 patients, at lowest 4/50 patients, above an arbitrary cutoff level.

In addition, the method being claimed is not the method in the cited reference. The instant diagnostic method comprises administration of a polypeptide to a subject and then detecting an immune response in said subject to said polypeptide. Amor et al does not administer the polypeptides to any subject. Amor et al tested sera from TB patients or control patients having lung disease other than TB for antibody levels which bind to the proteins. The instant claims recite that the method can also be performed with a "functional segment" of the polypeptide. Amor et al only utilized the whole polypeptide. Amor et al does not teach that the polypeptides can be utilized to diagnose a subject who is "susceptible" to *M. tuberculosis*, as is claimed in the instant invention.

Art Unit: 1645

Therefore, because the methods taught by Amor et al are not the same as that being claimed and the evidence that the polypeptides by themselves do not distinguish TB patients, the rejection is maintained.

7. The rejection of claims 1-8 and 11-20 under 35 U.S.C. 112, second paragraph, indefiniteness for specific properties and number/identity of conservatively substitutes residues, is maintained.

Applicants argue that those skilled in the art were entirely familiar with methods for assessing protein antigenicity and immunogenicity, but in order to expedite prosecution of the instant application, applicants have deleted embodiments specifying variants containing conservative substitutions from the claims.

The examiner has considered applicants' argument in light of the amendment of the claims, and withdraws the part of the rejection dealing with identity/number of conservative substitutions.

Applicants argue that one skilled in the art, at the priority date of the instant application, would have expected that a substantial number of the polypeptides would have *M. tuberculosis* specific antigenic and immunogenic properties and would certainly have known how to test for them. Applicants cite the reference of Amor et al as support for their argument.

The examiner has considered applicants argument, but does not find it persuasive. As stated in the original rejection, the specification does not provide guidance to which sequences and resulting polypeptides have the claimed *M. tuberculosis* specific antigenic and immunogenic properties.

Art Unit: 1645

The cited reference, Amor et al, does not support applicants argument, but actually teaches away from the claimed polypeptides possessing *M. tuberculosis* specific antigenic and immunogenic properties (see discussion of Amor et al, *supra*).

Therefore, the rejection is maintained concerning indefiniteness of the identity of *M. tuberculosis* specific antigenic and immunogenic properties.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. This application contains claims 21-36 drawn to a nonelected invention. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

Art Unit: 1645

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (571)272-0864.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



RODNEY P. SWARTZ, PH.D.
PRIMARY EXAMINER

Art Unit 1645

December 21, 2005